

K180028 Cook 810 Set, Desilets-Hoffman Introducer SetMay 2, 2018
119 days to decisionK180028 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Jan 3, 2018
Decision date	May 2, 2018
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Carly Powell
510(k) history	175 submissions · 153 cleared · 2006-2024

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